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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,823	08/22/2001	Corrado Fogher	B-4075PCT 618484-4	8610

36716 7590 10/11/2005

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,823

Applicant(s)

FOGHER, CORRADO

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 22, 2005 and July 11, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59,61,63,68,69,71,73,78-85 and 91-97 is/are pending in the application.
- 4a) Of the above claim(s) 92-97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 59,61,63,68,69,71,73,78-85 and 91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The Amendments filed April 22, 2005 and July 11, 2003 have been entered.

Claims 1-58, 60, 62, 64-67, 70, 72, 74-77 and 86-90 are cancelled.

Claims 59, 61, 63, 71, 73, 78-79, 81-82 and 84 are currently amended.

Claims 91-97 are newly added.

Claims 59, 61, 63, 68-69, 71, 73, 78-85 and 91-97 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

Newly submitted claims 92-97 are directed to an invention that is independent or distinct from the invention originally elected for the following reasons: the originally elected invention of Group V was directed to a plant expression cassette including the 7s basic globulin promoter and plants comprising said expression cassette, and to a method of using said expression cassette for plant transformation. Newly submitted claims 92-97 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A) The invention has no special technical feature that defined the contribution over the prior art, or

B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

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- 1) A product and a special process of manufacture of said product.
- 2) A product and a process of use of said product.
- 3) A product, a special process of manufacture of said product, and a process of use of said product.
- 4) A product and an apparatus specially designed to carry out said process.
- 5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

A) The technical feature linking the invention of originally elected Group V and newly submitted claims 92-97 is a plant expression cassette that expresses in seed with tissue-specific expression a non-degraded human lactoferrin, said cassette comprising a gene encoding human lactoferrin, said gene being operatively linked to DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic globulin, However, such an expression cassette is obvious over Salmon V. et al. (Production of Human Lactoferrin in Transgenic Tobacco Plants, Protein Expression and Purification, Volume 13, Issue 1, Pages 127-135, June 1998, Applicant's IDS) in view of Parmenter D.L. et al. (Production of biologically active hirudin in plant seeds using oleosin partitioning. Plant Mol Biol. 1995 Dec;29(6):1167-80) and van der Geest A. et al. (A 68 bp element of the beta-phaseolin promoter functions as a seed-specific enhancer. Plant Mol Biol. 1996 Nov;32(4):579-88), and therefore does not constitute a special technical feature as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. The special technical feature of each of newly submitted claims 92-97 is the particular method or product characteristic of each claim.

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and B) The allowed combinations do not include multiple products (nutriceutical) or multiple methods of using products (lactoferrin production methods, flour production method, functional food production method), as claimed in claims 92-97; See MPEP § 1850.

Applicant's claims do not have a special technical feature which links the inventions one to the other, and they encompass additional product and multiple methods of using products, and they thus lack unity of invention.

Since applicant has received an action on the merits for the originally presented invention, claims 92-97 are withdrawn from consideration as being directed to non-elected inventions.

Claim Rejections - 35 USC § 112

Claims 59, 61, 63, 68, 69, 71, 73 and 78-85 remain rejected, and claim 91 is rejected, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed December 22, 2004.

Applicant's arguments filed April 22, 2005 and July 11, 2003 have been fully considered but they are not persuasive.

Applicant points out that the present application discloses the amino acid sequence of the human lactoferrin (see SEQ. ID. NO. 1) and a synthetic DNA sequence with codons selected for expression in plant coding the same. Applicant also points to MPEP 2163.II.A.3(a)ii. Which

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states that “in the molecular biology arts, if an applicant disclosed an amino acid sequence. it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an' amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence”.

Applicant additionally points to *In Re David Wallach* (03-1327, Serial No. 08/485,129, August 11 2004), wherein the Court states that there is "no reason to require a patent applicant to list every possible permutation of the nucleic acid sequences that can encode a particular protein for which the amino acid sequence is disclosed, given the fact that it is, as explained above, a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it”. In view of the above, the Applicant respectfully submits that the DNA sequence coding human lactoferrin of the expression cassette should not be limited to those specifically disclosed in the application.

Applicant's arguments are unconvincing. First, with respect to the description of the human lactoferrin sequence, the Examiner maintains that the outstanding rejection was not predicated on a failure to disclose a representative number of nucleic acid sequences encoding the amino acid sequence encoded by the nucleic acid of SEQ ID NO:1, as such sequences are presumed to be described given that the genetic code is both universal and widely known; the outstanding rejection was predicated in part on a failure to disclose a representative number of nucleic acid sequences encoding unspecified human lactoferrin amino acid sequences. In this regard it is noted that claims 59, 61, 63, 69, 71, 73, 79-85 and 91 make no reference to the amino

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acid sequence of the encoded human lactoferrin, and Applicant has not presented any claims directed to the amino acid sequence encoded by the nucleic acid of SEQ ID NO:1.

Second, the outstanding rejection was not solely predicated on a failure to disclose a representative number of nucleic acid sequences encoding unspecified human lactoferrin amino acid sequences. The outstanding rejection was also predicated on a failure to disclose a representative number of regulatory sequences (i.e. soybean protein 7S basic globulin promoter and leader sequences). In this regard it is noted that MPEP 2163.II.A.3(a)ii and *In Re David Wallach* are not applicable to such sequences, since there is no universal genetic code that can be applied to regulatory sequences. In this regard it is also noted that claims 59, 68, 69, 78-85 and 91 make no reference to the nucleotide sequences of the soybean protein 7S basic globulin promoter and leader. In this regard it is additionally noted that Watanabe Y. et al. (Nucleotide sequence of the basic 7S globulin gene from soybean. *Plant Physiol.* 1994 Jul;105(3):1019-20, Applicant's IDS) indicate that Southern hybridization analysis suggests at least four copies of genes encoding 7S basic globulin may be present in the soybean genome (page 1020 paragraph spanning columns 1 and 2), yet Applicant describes promoter and leader nucleotide sequences obtained from a single soybean 7S basic globulin gene.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 91 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 91 is indefinite in the recitation of "suitable". It is unclear what type of

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biolistic system would be "suitable" for practicing the claimed invention, as suitability is context dependent, and neither the claims nor the specification indicate the criteria for suitability.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 59, 69, 79-85 and 91 are rejected under 35 U.S.C. 102(e) as being anticipated by Legrand et al. (U.S. Patent No. 6,569,831 B1, filed May 4, 1998 and issued May 27, 2003).

The claims are drawn to a recombinant DNA vector and plant expression cassette that expresses in seed with tissue-specific expression a non-degraded human lactoferrin, said cassette comprising a gene encoding human lactoferrin, said gene being operatively linked to DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic

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globulin, and to a method for using said vector to transform vegetal cells, and to vegetal cells and plants transformed with said vector.

Legrand et al. teach recombinant DNA vectors and plant expression cassettes that express in seed with tissue-specific expression a non-degraded human lactoferrin, said cassettes comprising a gene encoding human lactoferrin (column 9 lines 35-38; column 32 claims 20-32), said gene being operatively linked to DNA sequences coding for the radish cruciferin gene promoter and leader sequences, the *Arabidopsis* seed reserve protein genes GEA1 and GEA6 promoter and leader sequences, and the maize gamma zein gene promoter and the leader sequences (column 7 line 53 to column 8 line 12), and a method for using said vector to transform vegetal cells, and vegetal cells and plants transformed with said vector (column 15 line 5 to column 21 line 15; columns 29 to column 32 claims 1-19). The DNA sequences coding for the promoter and the leader sequences of the radish cruciferin gene, the *Arabidopsis* seed reserve protein genes GEA1 and GEA6 and the maize gamma zein gene promoter taught by Legrand et al. are the same as DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic globulin, since a name such as “of soybean protein 7S basic globulin” imparts no particular structural characteristics to a promoter or leader polynucleotide, such that any promoter and leader polynucleotides that express in seed with tissue-specific expression an operatively linked gene are the same as promoter and leader polynucleotides “of soybean protein 7S basic globulin”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 59, 69, 79-85 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salmon V. et al. (Production of Human Lactoferrin in Transgenic Tobacco Plants, Protein Expression and Purification, Volume 13, Issue 1, Pages 127-135, June 1998, Applicant's IDS) in view of Parmenter D.L. et al. (Production of biologically active hirudin in plant seeds using oleosin partitioning. Plant Mol Biol. 1995 Dec;29(6):1167-80) and van der Geest A. et al. (A 68 bp element of the beta-phaseolin promoter functions as a seed-specific enhancer. Plant Mol Biol. 1996 Nov;32(4):579-88).

The claims are drawn to a recombinant DNA vector and plant expression cassette that expresses in seed with tissue-specific expression a non-degraded human lactoferrin, said cassette comprising a gene encoding human lactoferrin, said gene being operatively linked to DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic globulin, and to a method for using said vector to transform vegetal cells, and to vegetal cells and plants transformed with said vector.

Salmon V. et al. teach recombinant DNA vectors and plant expression cassettes comprising a gene encoding human lactoferrin, said gene being operatively linked to an enhanced 35S promoter of CaMV and either a polynucleotide encoding a signal peptide of human lactoferrin, or a polynucleotide encoding a signal peptide of sporamin (page 130 Figure

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1). Salmon V. et al. also teach the production of transgenic tobacco plants by transforming tobacco cells with said cassettes and vectors by *Agrobacterium*-mediated transformation of tobacco leaf discs, which process inherently involves cellular aggregations including calluses capable of regenerating transgenic plants (page 128 column 2 second full paragraph; page 130 column 1 *Generation of hLF-Expressing Transgenic Tobacco Plants*). The human lactoferrin expressed by the plants was non-degraded (page 132 paragraph spanning columns 1 and 2).

Salmon V. et al. do not teach a recombinant DNA vector and plant expression cassette that expresses in seed with tissue-specific expression, or DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic globulin.

Parmenter D.L. et al. teach a recombinant DNA vector and plant expression cassette that expresses an oleosin-hirudin fusion protein in seed with tissue-specific expression (page 1169 Figure 1; page 1173 Figures 2 and 3; page 1174 Figures 4 and 5; page 1175 Figures 6 and 7; page 1176 Table 1 and Figure 8). Parmenter D.L. et al. also teach that seed-based expression systems had recently become the focus for plant based expression studies directed to the production of recombinant proteins in plants, as seeds possess a number of characteristics that make them highly suitable for this purpose (page 1168 column 1 first paragraph).

van der Geest A. et al. teach DNA sequences coding for the promoter and the leader sequences of the [beta]-phaseolin (phas) gene, which encodes the major storage protein in bean (*Phaseolus vulgaris* L.) (page 582 Figure 1). van der Geest A. et al. also teach that the leader sequences of the [beta]-phaseolin (phas) gene expresses in seed with tissue-specific expression an operatively linked reporter gene (page 584 Figure 3; page 585 Figure 4). The DNA sequences coding for the promoter and the leader sequences of the [beta]-phaseolin (phas) gene taught by

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van der Geest A. et al. are the same as DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic globulin, since a name such as “of soybean protein 7S basic globulin” imparts no particular structural characteristics to a promoter or leader polynucleotide, such that any promoter and leader polynucleotides that express in seed with tissue-specific expression an operatively linked gene are the same as promoter and leader polynucleotides “of soybean protein 7S basic globulin”.

Given the success of Salmon V. et al. in expressing a non-degraded human lactoferrin in plant cells using plant expression vectors, given the success of Parmenter D.L. in expressing an oleosin-hirudin fusion protein in seed with tissue-specific expression using a plant expression vector, and the teaching of Parmenter D.L. that seeds possess a number of characteristics that make them highly suitable for the production of recombinant proteins in plants, and given the success of van der Geest A. et al. in expressing a reporter gene in seed with tissue-specific expression using a plant expression vector comprising a reporter gene operatively linked to DNA sequences coding for the promoter and the leader sequences of the [beta]-phaseolin (phas) gene, which are the same as DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic globulin, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to express in seed with tissue-specific expression a non-degraded human lactoferrin using a plant expression cassette that comprises a gene encoding human lactoferrin operatively linked to DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic globulin. One skilled in the art would have been motivated to do so in order to produce recombinant lactoferrin in plant seed. One skilled in the art would have had a reasonable expectation of success given the success of Salmon V. et al. in

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expressing a non-degraded human lactoferrin in plant cells, given the success of Parmenter D.L. in expressing an oleosin-hirudin fusion protein in seed with tissue-specific expression, and given the success of van der Geest A. et al. in expressing a reporter gene in seed with tissue-specific expression. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Remarks

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Examiner
Art Unit 1638

CC


9/28/05